

## Message Text

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PAGE 01 STATE 058687  
ORIGIN HEW-06

INFO OCT-01 EA-09 NEA-10 ISO-00 OES-06 /032 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK  
APPROVED BY OES/APT/BMP: WJWALSH, III  
DHEW/PHS/OASH/OIH: RFISCHER  
NEA/IAI:MANDERSON(INFO)  
EA/ANP:HTNELSON(INFO)

-----170030Z 070661 /20

P 162206Z MAR 77  
FM SECSTATE WASHDC  
TO AMEMBASSY CANBERRA PRIORITY  
AMEMBASSY TEL AVIV PRIORITY

UNCLAS STATE 058687

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, AS, IS

SUBJECT: EXTENSION RECALL ON INTRAOCULAR IRIS PLANE  
LENS (RECALL T-019-7)

1. FDA ADVISES OF THE FOLLOWING PRODUCT RECALL EXTENSION:

PRODUCT INVOLVED:

COPELAND INTRAOCULAR IRIS PLANE LENS FOR IMPLANTATION INTO  
THE EYE TO REPLACE A CATARACT-DAMAGED LENS. EACH POLY-  
METHYL METHACRYLATE LENS IS PACKED IN A SEALED GLASS VIAL  
CONTAINING APPROXIMATELY 3CC'S OF SODIUM BICARBONATE SOL-  
UTION. FROM 1-3 VIALS ARE PACKED IN A PLASTIC SHIPPING  
CASE WITH A LABELING INSERT. ALL, REPEAT ALL, DIOPTRIC  
POWERS ARE UNDER RECALL.

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 058687

PRODUCT IDENTIFICATION:

A. VIAL CONTAINING LENS LABELED "ONE INTRAOCULAR LENS -  
STERILE - IN SODIUM BICARBONATE 5.0 PERCENT SOLUTION -  
COPELAND INTRA LENSES INC., N.Y., N.Y. 10021". THE VIAL  
LABEL ALSO LISTS THE LOT NUMBER OF THE LENS AND THE

DIOPTER POWER. THE PLASTIC SHIPPING CASE LABEL READS IN PART: "INTRAOCULAR LENSES STERILE-IN A SEALED CONTAINER XXX MADE BY COPELAND INTRA LENSES INC., 129 EAST 61 ST., N.Y., N.Y. 10021".

B. EACH LENS, WHEN SHIPPED, IS ASSIGNED A LENS SERIAL NUMBER WHICH IS ETCHED INTO THE VIAL CRIMP TOP AND WHICH IS WRITTEN ON THE SHIPPING CASE. THE LOT NUMBER APPEARS ONLY ON THE VIAL LABEL. ALL, REPEAT ALL, LOT NUMBERS ARE UNDER RECALL EXCEPT LOTS 2327, 2366, 2289, 76334, 76335, 76368 AND 76371. NOTE: PRIOR TO 1974, TORIGIAN DID NOT LABEL THE VIALS WITH LOT NUMBERS. THEREFORE, ALL VIALS, REPEAT ALL VIALS, WHICH DO NOT BEAR LOT NUMBERS ARE ALSO UNDER RECALL. THE LOTS NOT UNDER RECALL ARE NEW PRODUCTION WHICH WERE INDEPENDENTLY TESTED FOR STERILITY PRIOR TO SHIPMENT.

MANUFACTURER/RECALLING FIRM:

COPELAND INTRA LENSES, INC.  
129 EAST 61 STREET  
NEW YORK, NEW YORK 10021

COPELAND MANUFACTURED THE LENSES. THE LENSES WERE STERILIZED AND PACKED IN TWO VIALS BY A CONTRACT FIRM: TORIGIAN LABS, INC., 218-20 98TH AVENUE, QUEENS VILLAGE, NEW YORK 11429. ALL OF THE LENSES INVOLVED WERE DISTRIBUTED BY COPELAND UNDER THEIR OWN NAME. TORIGIAN HAS STERILIZED THESE LENSES FOR COPELAND FOR THE LAST 8 TO 10 UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 058687

YEARS.

2. REASON FOR RECALL:

ON 16 NOVEMBER 1976 THE FIRM INSTITUTED A RECALL OF 5 RECENTLY DISTRIBUTED LOTS WHICH WERE FOUND TO BE NON-STERILE AND WERE CONTAMINATED WITH PSEUDOMONAS AERUGINOSA. IMPLANTED LENSES OF THESE LOTS RESULTED IN EYE INFECTIONS IN 9 PATIENTS WHO RECEIVE THE COPELAND LENS IMPLANTS. ON 22 DECEMBER 1976 THE FIRM EXTENDED THE RECALL TO A 6TH LOT WHICH WAS FOUND TO BE CONTAMINATED WITH PSEUDOMONAS ALCALIGENES. ON 6 JANUARY 1977 THE FIRM RECEIVED A LETTER FROM FDA REQUESTING THAT THEY RECALL ALL LOTS PREVIOUSLY DISTRIBUTED BY THEM WHICH WERE PROCESSED BY TORIGIAN LABS. THE FDA REQUEST WAS INITIATED BECAUSE THE FIRM MAY HAVE UNDERESTIMATED THE

THE NUMBER OF UNIMPLANTED LENSES REMAINING ON THE MARKET OF OTHER PREVIOUSLY DISTRIBUTED LOTS, AND BECAUSE THE

ABSENCE OF ADVERSE REACTIONS REPORTS IS NO GUARANTEE  
OF STERILITY.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES  
TO DETERMINE IF THEY HAVE RECEIVED RECALL LETTER FROM  
COPELAND DATED 10 JANUARY 1977. ANY QUESTIONS CONSIGNEES  
MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED TO  
MR. MICHAEL J. COPELAND, PRESIDENT, COPELAND INTRA LENSES  
INC., 129 EAST 61 STREET, NEW YORK CITY, N.Y. 10021,  
TELEPHONE 212-838-3525.

4. FOREIGN CONSIGNEES AS FOLLOWS:

ROYAL PRINCE ALFRED HOSPITAL  
MISSENDEN ROAD  
CAMPERDON, AUSTRALIA NSW2050

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PAGE 04 STATE 058687

SAARE ZETEK HOSPITAL  
161 JAFFA STREET  
POST OFFICE BOX 293  
JERUSALEM, ISRAEL

NEGEZ GENERAL HOSPITAL  
P.O.B. 51  
BEEBER SHEBA, ISRAEL  
VANCE

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL CARE, EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 16-Mar-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
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**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE058687  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** JRWEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770090-1198  
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**Legacy Key:** link1977/newtext/t19770354/aaaabvce.tel  
**Line Count:** 148  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** 11e080b7-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 3  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
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**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 3091531  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** EXTENSION RECALL ON INTRAOCULAR IRIS PLANE LENS (RECALL T-019-7)  
**TAGS:** OGEN, ETRD, TBIO, AS, IS, US, COPELAND INTRA LENSES INC, TORIGIAN LABS INC  
**To:** CANBERRA TEL AVIV  
**Type:** TE  
**vdkgvwkey:** odb://SAS/SAS.dbo.SAS\_Docs/11e080b7-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009